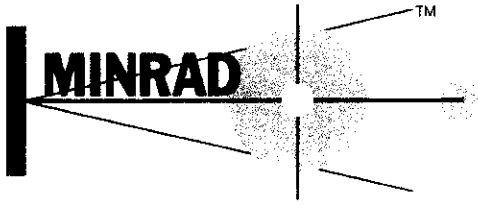
K072255

OCT 18 2007

5.0 510(k) Summary



510(k) Summary

1.	**510(k) owner's name:**	MINRAD Inc.
2.	**Address:**	50 Cobham Drive Orchard Park, NY 14127 Phone: (716) 855 1068 Facsimile: (716) 855 1078
	Contact:	John McNeirney, Senior Vice President & Chief Technical Officer
3.	**Preparation Date:**	August 10th, 2007
4.	**Device name:**	Nasal Scavenging Circuit
5.	**Common name:**	Gas Scavenging Apparatus
6.	**Product classification:**	Gas-Scavenging Apparatus (21 CFR 868.5430, Product Code CBN)
7.	**Predicate device:**	Fraser Harlake Dental Anti-Pollution System (K833692)
8.	**Description of device:**	The single-use Nasal Scavenging Circuit is designed for the removal of patient expired and excess gases during conscious sedation procedures. For proper operation, the scavenger mask must be connected to a vacuum source capable of providing at least 45 LPM of vacuum flow, at an operating vacuum pressure of 8 in Hg as indicated by the National Institute for Occupational Safety and Health (NIOSH) Publication No. 94-129, September 1994. The vacuum source should vent exhaust gases to the outside of the building, away from fresh air intakes, windows, or walkways.

9.	**Voluntary standards:**	Performance Standards have not been promulgated for this device, however pertinent sections of the standards listed below were followed during the design of the device: • National Institute for Occupational Safety and Health (NIOSH) Publication No. 94-129 Technical Report – Control of Nitrous Oxide in Dental Operatories • International Standards Organization ISO 5356-1: 2004(E) Anaesthetic and respiratory equipment – conical connectors, Part 1: Cones and sockets • International Standards Organization ISO 5367:2000(E) Breathing Tubes intended for use with anaesthetic apparatus and ventilators • American National Standards Institute ANSI Z79.11-1982 for anesthetic equipment – scavenging systems for excess anesthetic gases • CGA V-5 – 2005 Diameter Index Safety System (DISS) (Non-interchangeable Low Pressure Connections for Medical Gas Applications)
10.	**Intended use:**	For Relative Analgesia [Conscious Sedation]
11.	**Indication for Use:**	This disposable device is to be used in conjunction with conscious sedation systems for the delivery to a patient a mixture of analgesic agent and oxygen gases, or analgesic agent and air, for the removal from the treatment location of gases expired by the patient, and removal from the treatment location any excess gases delivered to a patient. The device is supplied non-sterile and latex-free.
12.	**Technological characteristics:**	The indications for use, the technology, and the performance specifications are the same for the Nasal Scavenging Circuit and the predicate device.
13.	**Non-Clinical Testing**	In order to verify that the Nasal Scavenging Circuit does not raise new issues of safety or effectiveness and, thus, is substantially equivalent to the predicate device, bench testing was performed. These tests confirmed that the device causes no additional safety issues for the patient.

This concludes the 510(k) summary.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 18 2007

Mr. John McNeirney
Vice President and Chief Technical Officer
MINRAD, Incorporated
50 Cobham Drive
Orchard Park, New York 14127

Re: K072255
Trade/Device Name: Nasal Scavenging Circuit
Regulation Number: 21 CFR 868.5430
Regulation Name: Gas-Scavenging Apparatus
Regulatory Class: II
Product Code: CBN
Dated: October 12, 2007
Received: October 15, 2007

Dear Mr. McNeirney:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

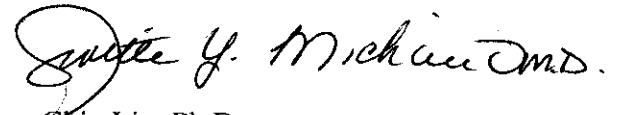
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Additional information per 510(k) response letter received August 31, 2007 from Dr. Chiu Lin: ISSUE 1, ATTACHMENT 1 K072255

4.0 Indications for Use Statement

Indications for Use

510(k) Number (if known): _____

Device Name: Nasal Scavenging Circuit

Indications for Use:

The single-use Nasal Scavenging Circuit is intended to be used in conjunction with a conscious sedation system for the delivery of medical gases to the patient, and for the removal of expired, excess and unused gases from the treatment location.

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K072255

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)